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United States District Court,N.D. Illinois, Eastern Division.
MORTON GROVE PHARMACEUTICALS, INC., Plaintiff and Counter-defendant,
v.
PAR PHARMACEUTICAL COMPANIES, INC. and Par Pharmaceutical, Inc., Defendants and Counter-plaintiffs.
No. 04 C 7007.

March 28, 2006.

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MEMORANDUM OPINION AND ORDER
GUZMÁN, J.
***1** Plaintiff Morton Grove Pharmaceuticals, Inc. ("MGP") brings this action against defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"). In Counts I through V of its Amended Complaint, MGP seeks a declaratory judgment of noninfringement and unenforceability of U.S. Patent Nos. 6,028,065 ("the '065 patent"), 6,268,356 ("the '356 patent"), 6,593,318 ("the '318 patent") and 6,593,320 ("the '320 patent"). In Count VI, MGP alleges violation of the Sherman Act, 15 U.S.C. § 1 *et seq.*, and seeks treble damages and injunctive relief. Par now moves to dismiss Count VI of MGP's Amended Complaint for failure to state a claim upon which relief may be granted, pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). For the reasons below, the Court denies the motion.

FACTS

The following facts, taken from MGP's complaint, are accepted as true for the purposes of this motion. This action arises under the patent and antitrust laws of the United States and this court has subject matter jurisdiction pursuant to 28 U.S.C. § § 1331, 1337, and 1338 and 15 U.S.C. § § 15 and 26. (Am.Compl.¶ 4.) MGP and Par develop and market generic versions of pharmaceuticals. (*Id.* ¶ ¶ 14-16.) In the late 1990's, several generic pharmaceutical manufacturers including Par, sought FDA approval to market a generic version of Bristol-Myers Squibb's megestrol acetate oral suspension drug. (*Id.* ¶ 117.) Bristol-Myers developed and marketed the branded version of megestrol acetate and was the sole supplier of the drug for a number of years. (*Id.*) Megestrol acetate is useful for treating anorexia, cachexia, and significant unexplained weight loss. (*Id.* ¶ 116.)

Par was the first to file an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of megestrol acetate. (*Id.* ¶ 118.) The FDA approved Par's ANDA. (*Id.*) In 2003, MGP filed an ANDA with the FDA to market its generic version of megestrol acetate. (*Id.* ¶ 12.) In expectation of FDA approval, which was received on November 1, 2004, MGP undertook preparations to manufacture and sell megestrol acetate. (*Id.* ¶ ¶ 13-14.) Likewise, other generic manufacturers, including Roxane Laboratories and Teva Pharmaceuticals, sought and received FDA approval to market generic versions of the drug. (*Id.* ¶ ¶ 117-18.)

Par is the assignee and exclusive licensee of the '065, '356, '318 and '320 patents (collectively, "the Par Patents") which claim a composition for a megestrol acetate oral suspension product as well as uses and methods of manufacture of the composition. (*Id.* ¶ ¶ 6-11.) On May 7, 2004, prior to FDA approval of MGP's ANDA, Par's counsel sent a letter to MGP concerning the Par Patents. (*Id.* ¶ 15.) The letter requested that MGP provide details of its product formulation and method of manufacture prior to launching its megestrol acetate product and urging MGP not to launch its product until Par had an opportunity to evaluate the formulation and manufacturing information. (*Id.* ¶ 16.) Par also contacted MGP to urge them to withdraw their ANDA to avoid litigation. (*Id.* ¶ 17.)

***2** Par has sought to enforce the Par Patents against

other generic manufacturers of megestrol acetate. (*Id.* ¶ ¶ 18-21.) In 2002, Par filed a complaint against Alpharma U.S. Pharmaceuticals Division seeking a declaration of infringement of the '065 and '356 patents. (*Id.* ¶ 19.) In 2003, Par filed a complaint against Roxane Laboratories, Inc. alleging infringement of the '318 and '320 patents. (*Id.* ¶ 20.) In 2003, Teva Pharmaceuticals, U.S.A. and Copley Pharmaceutical, Inc. sought a declaratory judgment of non-infringement of the Par Patents and Par counterclaimed for infringement of the same patents. (*Id.* ¶ 21.)

MGP, believing it faced a patent infringement suit from Par for its manufacture and sale of megestrol acetate, filed the present suit for a declaratory judgment that MGP does not infringe the Par Patents and that the Par Patents are unenforceable. (*Id.* ¶ ¶ 22, 24, 26, 28, 30, 32.) Par counterclaimed that MGP infringes the '318 patent. (*Id.* ¶ 22.) Following discovery on the issues of patent infringement and enforceability, MGP filed an Amended Complaint adding Count V, alleging inequitable conduct in prosecution of the Par Patents, and Count VI for violation of the Sherman Act. (*Id.* ¶ ¶ 31-112, 113-34.) In turn, Par filed the present motion to dismiss Count VI for failure to state a claim.

In support of Count VI, MGP alleges that the Par Patents were procured by fraud on the U.S. Patent and Trademark Office ("PTO") and the patents would not have issued but for the fraud. (*Id.* ¶ 123.) MGP asserts that knowing and willful misrepresentations were made when Par and its agents omitted and misrepresented material information to the PTO during the prosecution of the Par Patents with the intent to deceive the patent examiner. (*Id.*)

MGP also alleges that Par's patent infringement suits against it and other competitors are baseless in light of the alleged fraud upon the PTO. Consequently, MGP alleges that Par's litigation is a sham, being brought for the purpose and with the specific intent of monopolizing the market for megestrol acetate oral suspension products by raising the cost of doing business in the market, extorting settlements that limit output and deterring customers from purchasing competitive products. (*Id.* ¶ ¶ 119, 122, 127.)

MGP further alleges that Par and others acting on their behalf monopolized or attempted to monopolize the U.S. market for megestrol acetate oral suspension products beginning in 1998 and continuing through the present. (*Id.* ¶ ¶ 115, 121.) Specifically, MGP asserts that Par gained a controlling share of the generic submarket in 2002 and that Par controlled in excess of seventy-five percent of the generic market for megestrol acetate in 2003 and 2004. (*Id.* ¶ 118.) MGP alleges that Par has the specific intent to monopolize the market as demonstrated by bringing baseless law suits, limiting output in the market and maintaining artificially high prices through licenses that limit the output of competitors. (*Id.* ¶ 128.)

***3** MGP asserts that if this scheme succeeded, it would pose a dangerous probability of monopolizing the market and generic submarket for megestrol acetate. (*Id.* ¶ 131.) MGP states that Par's actions have damaged its business through lost sales and legal fees. (*Id.* ¶ 132.) Furthermore, Par has restricted output, raised competitor costs, raised the cost of entry of would-be competitors, and increased the market price for generic megestrol acetate. (*Id.* ¶ 134.)

DISCUSSION

A motion to dismiss pursuant to Rule 12(b)(6) should not be granted "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The complaint must contain either direct or inferential allegations concerning every element necessary for recovery under the relevant legal theory. *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir.1984). An antitrust plaintiff cannot allege bare legal conclusions but must provide facts that "at least outline or adumbrate" a violation of the Sherman Act. *Car Carriers*, 745 F.2d at 1106. In deciding the motion to dismiss, the court draws all reasonable inferences in MGP's favor and views all factual allegations in the complaint as true. *See Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir.2004).

Section two of the Sherman Act is violated by monopolizing, attempting to monopolize, or combining or conspiring with others to monopolize interstate or foreign commerce. 15 U.S.C. § 2. MGP alleges that Par has monopolized or attempted to monopolize the market and generic submarket for megestrol acetate oral suspension products in the United States.

In addition to setting forth the elements of an antitrust claim, MGP must also present allegations sufficient to strip Par of its antitrust immunity. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071

(Fed.Cir.1998). A patentee who conforms to the patent laws in procuring and enforcing a patent enjoys immunity from the antitrust laws. *Simpson v. Union Oil Co.*, 377 U.S. 13, 24, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964). Nonetheless, a patentee may be stripped of its immunity when it is alleged that its patent was obtained through knowing and willful fraud on the PTO. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965). Alternatively, immunity is also destroyed when a patentee brings a patent infringement suit that comes within the sham litigation exception of the *Noerr-Pennington* doctrine. *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 59-60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993) (*"PRE"*); *United Mine Workers v. Pennington*, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) (*"Pennington"*); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137-44, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (*"Noerr"*). Each ground is an independent basis for stripping a patent owner of immunity from the antitrust laws. *Nobelpharma*, 141 F.3d at 1071.

***4** MGP asserts that the Par Patents were obtained through fraud on the PTO and that Par has engaged in sham litigation. The Court addresses each ground in turn.

I. The *Walker Process* Claim

Antitrust liability under *Walker Process* arises when a patentee attempts to enforce a patent that: (1) has been procured by knowing and willful fraud and the subject matter of the patent is not otherwise patentable and (2) allows the patentee to dominate a real market. *Walker Process*, 382 U.S. at 177; *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir.1984). The usual elements of an antitrust claim must also be present. *Walker Process*, 382 U.S. at 174. The Court of Appeals for the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law," *Nobelpharma*, 141 F.3d at 1068 (en banc). [FN1] The law of the regional circuit controls as to the other elements of the antitrust claim such as the relevant market, market power, restraint on competition, and other issues not unique to patent law. *Id.*

FN1. The issue of "choice of circuit" law overturned Federal Circuit precedent and that portion of the opinion was therefore decided en banc.

A. Fraudulent Procurement of the Patents

Fraud under *Walker Process* is distinguishable from the lesser offense of inequitable conduct before the PTO, which may merely render a patent unenforceable. *Id.* at 1069. The Federal Circuit equates fraud under *Walker Process* with the common law definition of fraud. *Id.* Fraud in the context of patent prosecution consists of:
(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which the misrepresentation or deliberate omission the patent would not have been granted.

C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed.Cir.1998). Intent to deceive can be found where the state of mind is so reckless as to the consequences that it is the equivalent of intent. *Nobelpharma*, 141 F.3d at 1070. Merely failing to cite a reference to the examiner does not amount to procurement of a patent by fraud. *Id.* at 1071.

An allegation of fraudulent procurement of a patent is subject to the pleading requirements of Federal Rule of Civil Procedure ("Rule") 9(b). *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed.Cir.2005), *cert. granted*, No. 05-608, 2006 WL 386375 (U.S. Feb.21, 2006). Rule 9(b) states that in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity but malice, intent, knowledge, and other condition of mind may be averred generally. Fed. R. Civ. P. 9(b). Allegations of fraud must be concrete and particularized enough to provide the defendants with notice and allow them to prepare a defense. *Allen-Bradley Co., Inc. v. Autotech Corp.*, No. 86 C 8514, 1990 WL 16453, at *2 (N.D.Ill. Feb.8, 1990). Nevertheless, Rule 9(b) must be read in harmony with the relatively liberal pleading standards of Rule 8. *Id.* at *2-3. Therefore, the Court looks to the Amended Complaint to determine if each of the elements of fraud has been adequately set forth with respect to the Par Patents.

1. The '065 Patent

***5** MGP alleges that Par failed to disclose: (1) the Bristol-Myers' parent patent application and made

statements to the PTO inconsistent with those made in litigation with Bristol-Myers; (2) other material prior art references that directly refuted Par's arguments as to patentability; and (3) material experimental results. (Am.Compl.¶ 32.) First, MGP asserts that during prosecution of the '065 patent, Par was aware of and did not disclose the parent application, U.S. Patent App. 07/717,155 ("the '155 application"), of Bristol-Myers' U.S. Patent No. 5,338,732 ("the '732 patent") for megestrol acetate oral suspension product.[FN2]

> FN2. The '732 patent issued from an application which was a continuation-in-part of the 07/839,016 application, which was in turn a continuation of the 07/717,155 application.

Following rejection by the examiner of all the claims in the application for the '065 patent in light of the '732 patent, Par argued that the '732 patent discloses that only surfactants having properties similar to polysorbate 80 could be used while their claims were distinguishable from the '732 patent in that surprising results using surfactants other than polysorbate were achieved. (*Id.* ¶ 44.) Shortly thereafter, the PTO issued a Notice of Allowability for Par's claims. (*Id.* ¶ 46.) During prosecution, Par did not disclose the '155 application that was the parent application of the '732 patent, which discloses that surfactants other than polysorbate can be substituted, including a surfactant claimed by Par in the '065 patent. (*Id.* ¶ 50.)

MGP also alleges that Par relied on the disclosure of other surfactants in the '155 application in an earlier suit brought by Bristol-Myers against Par for infringement of the '732 patent. An applicant has a obligation to disclose to the examiner material information that comes to an applicant's attention as a result of assertions in a lawsuit and any assertion that is made by a litigant that is contradictory to those made to the patent examiner is material information that should be brought to the attention of the examiner. *Golden Valley Microwave Foods v. Weaver Popcorn Co.*, 837 F.Supp. 1444, 1474 (N.D.Ind.1992). MGP asserts that Par's argument made in the prior litigation that various surfactants were dedicated to the public is inconsistent with statements made to the PTO that the claims in its application reciting various surfactants were patentable over the '732 patent which teaches that only polysorbate is an effective surfactant. (Am.Compl.¶ 54.) In that suit, Par argued on appeal to the Federal Circuit that surfactants that were disclosed in the '155 application but not claimed in the '732 patent were dedicated to the public and precluded infringement. (*Id.* ¶¶ 51-53.)

MGP also alleges that Par was aware of U.S. Patent No. 4,402,695 ("the Wong reference") and other prior art that directly refuted claims of patentability but did not cite the prior art during prosecution of the '065 patent. (*Id.* ¶ 56.) Par also relied on the Wong reference in arguments made in the litigation with Bristol-Myers. (*Id.* ¶ 58.) In its Amended Complaint, MGP provides the following examples of statements made by Par during the litigation:
***6** "It is undisputed that the Par ingredients [glycerin and docusate sodium] are listed in the prior-art Wong reference...."
"Wong was relied on for its showing that megestrol acetate could be formulated into a liquid or semi-liquid carrier, using ingredients that included polysorbate and polyethylene glycol, as well as glycerin and a number of other ingredients."

(*Id.* ¶ 59.) MGP asserts that the omitted Wong reference established a *prima facie* case of unpatentability and that Par took a position in prosecution of the '065 patent inconsistent with arguments made in prior litigation. (*Id.* ¶ 63.)

In sum, MGP alleges that the '065 patent is anticipated by the '155 application under 35 U.S.C. § 102 and therefore unpatentable. MGP also alleges that Par was aware of the '155 reference and knowingly omitted it, Par knowingly made inconsistent statements with respect to the '155 application and the Wong reference to secure patentability and but for Par's misrepresentations and omissions, the '065 patent could not have issued. Furthermore, Par's reliance on these references during the course of litigation with Bristol-Myers suggests that Par was aware of the potential significance of the references in relation to patentability of the '065 patent. MGP asserts that the prior art established a *prima facie* case of unpatentability and the '065 patent would not have issued but for the omissions of the references and/or the inconsistent position taken during prosecution with respect to the references. Based on these allegations, the Court holds that MGP has sufficiently set forth facts to support fraudulent procurement of the '065 patent.

Par argues that the amended claims of the '065 patent were distinguished from the '732 patent on grounds unrelated to the surfactant, and assuming that the reference had been material and was disclosed, the patent could still have issued. Par also contends that

the Wong reference may be material to Par's product but it is immaterial to the Par Patents. Nevertheless, MGP alleges "[t]he Wong reference was material in that, *according to defendants,* it discloses examples of drug products with megestrol acetate and a large number of other ingredients, including those *claimed in the '065 patent* ...." (*Id.* ¶ 57 (emphasis added).) Par may ultimately be correct on these points, but that conclusion cannot be reached on a motion to dismiss under Rule 12(b)(6). Only when plaintiff pleads itself out of court may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6). *Xechem,* 372 F.3d at 901. MGP has not done so. Therefore, MGP has adequately alleged that the '065 patent was procured by fraud.

2. The '356, '318 and '320 Patents

The '356 and '318 patents were issued from continuation applications of the parent application that ultimately issued as the '065 patent. Similarly, the '320 patent issued from a divisional application of the parent application. The duty of candor extends throughout the patent's entire prosecution history and a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application. *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803 (Fed.Cir.1990). Nevertheless, conduct that renders the parent patent unenforceable does not necessarily infect a divisional application where the claims in the divisional are unrelated to the prior art omitted during prosecution of the parent application. *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed.Cir.1998).

*7 MGP alleges that conduct during the prosecution of the parent application that issued as the '065 patent, discussed above, applies equally to the claims of the continuing applications that issued as the '356 and '318 patents and the divisional application that issued as the '320 patent. Par merely states that "the scope of the claims in the '318 and '320 patents differ in scope from the originally-filed '065 claims, but for different reasons" and "these claims too would be patentable even if Par were barred from enforcing them." (Def.'s Reply Mem. Supp. Mot. Dismiss at 8.) Viewing MGP's allegation as true, the subject matter of the claims of the parent application is related to subject matter contained in the claims of the '320, '356, and '318 patents, thereby making the alleged omissions and inconsistent positions taken during prosecution of the parent application applicable to the '320, '356, and '318 patents. Because fraudulent procurement has been adequately alleged with regard to the parent application and the subsequent applications are allegedly of related subject matter, MGP has adequately alleged fraud in the procurement of the '320, '356, and '318 patents in its Amended Complaint.

MGP further alleges, with respect to the '356 patent, that Par failed to disclose to the PTO documents from the Bristol-Myers litigation, including its brief in support of summary judgment of non-infringement, its appellate brief to the Federal Circuit, and the expert reports of Dr. Hem regarding the difficulty of formulating stable suspensions even though Par sought claims covering all surfactants based on a disclosure of only two surfactants. (Am.Com pl.¶ ¶ 81-82.) It is asserted that these documents were material, established *prima facie* unpatentability, and/or refuted or were inconsistent with the position Par took during prosecution of the patents. (*Id.* ¶ 83.)

The Court agrees with Par that these allegations, as stated, fail to allege with particularity representations or omissions to the PTO that amount to fraud in the procurement of the '356 patent. In particular, MGP does not point to any specific facts or contentions in the Bristol-Myers briefs that were material to patentability. Nor does MGP satisfactorily articulate how Dr. Hem's report that proclaimed the "difficulty" of creating stable compounds establish unpatentability. Nonetheless, as described above, MGP has satisfied the burden of pleading fraud in the procurement of the '356 patent by asserting the relatedness of the '356 patent and the '065 patent, making further allegations of fraud unnecessary.

With respect to the '318 and '320 patents, MGP further alleges that Par failed to disclose to a new examiner the rejections made by the examiner in the parent case. (*Id.* ¶ ¶ 91, 106-07.) During prosecution of the '318 patent, Par presented a second preliminary amendment to the PTO adding additional claims which were substantially similar in scope to the claims rejected in the prosecution of the '065 patent but omitted the limitations which the examiner had required in prosecution of the '065 and '356 patents. (*Id.* ¶ 92.) MGP alleges that in the amendment, Par stated a "series of new claims covering subject matter disclosed but not previously specifically claimed in this application or in the parent application/patents is being presented." (*Id.* ¶ 93.) Neither the earlier rejections nor the references which had been the basis of rejections were disclosed. (*Id.* ¶ 94.) Furthermore, following a Notice of Allowance, Par procured a Supplemental Notice of Allowance from the

examiner stating that the broader claims were fully examined and that the claims were neither disclosed nor suggested by the prior art. (*Id.* ¶ 97.)

*8 Par counters that MGP does not allege that the examiner lacked access to the prosecution history of the parent application that indicated the rejection and that statements made by the examiner in the parent case were not cumulative of information already before the examiner of the '318 patent. Par's suggestion that the duty of disclosure to the PTO articulated in 37 C.F.R. 1.56 (information is material to patentability when it is not cumulative of information already of record or being made of record in the application) does not require it to disclose earlier rejections or references is erroneous. "The individuals covered by 37 C.F.R. 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are material to patentability of the application in question." Manual of Patent Examination Procedure, 8th Ed., Rev. No. 2, § 2001.06(b). A contrary decision of another examiner reviewing substantially similar claims is material. *Id.* § 2004 ¶ 9; *see* *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69 (Fed.Cir.2003).

In addition to the incorporated allegations related to the '065 patent, MGP has presented further allegations of an omission of prior rejections of similar claims in a co-pending application. Without disclosure of the rejections, the examiner could have been induced to issue an allowance on those patents. Therefore, MGP has properly alleged an additional basis upon which the'318 and '320 patents were procured by fraud.

B. Dominance in a Real Market

In addition to alleging that the Par Patents were obtained by fraud, MGP must sufficiently allege that the patents permit Par to dominate a real market. To establish monopolization or an attempt to monopolize under the Sherman Act, it is necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved. *Walker Process*, 382 U.S. at 177. "Without a definition of that market, there is no way to measure [the defendant's] ability to lessen or destroy competition." *Id.* A market is defined as all products "reasonably interchangeable by consumers for the same purposes," because the availability of a substitute lessens a firm's ability to raise prices beyond a competitive level. *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 395, 76 S.Ct. 994, 100 L.Ed. 1264 (1956); *see* *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d. Cir.2004). Although the liberal pleading standard of Rule 8(a) applies, the Seventh Circuit requires the pleader to allege more than bare legal conclusions and to present facts that at least outline a violation of the Sherman Act. *Car Carriers*, 745 F.2d at 1106.

MGP asserts that the relevant market is the U.S. market for megestrol acetate oral suspension products and/or the generic submarket. (Am.Compl.¶ ¶ 118, 131.) Par was the first company to enter the generic market, gained a controlling share of the generic market in 2002, and accounted for in excess of seventy-five percent of the generic market in 2003 and 2004. (*Id.* ¶ 118.) Par obtained a majority of the market for brand-name megestrol acetate when it obtained a license from Bristol-Myers in 2002. (*Id.*) MGP alleges that Par has informed MGP and other competitors that they will license the Par Patents only on terms that limit their output. (*Id.* ¶ 128.) Par's patent enforcement actions have led to restricted output, raised costs, erected barriers to competition, and increased market price. (*Id.* ¶ 133.)

*9 Viewing these allegations as true, MGP has adequately pleaded that Par has power in a real market as a result of the Par Patents. First, MGP has sufficiently presented a real market. Whether the market is the overall market or the generic submarket for megestrol acetate oral suspension products is a question of fact. *See* *Eastman Kodak Co. v. Image Technical Servs.*, 504 U.S. 451, 482, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992) (market definition is an intensely factual determination and proper market definition can be determined only after a factual inquiry into the 'commercial realities' faced by consumers). Submarkets, such as the generic submarket of a pharmaceutical, may constitute a relevant market for antitrust analysis. *Geneva*, 386 F.3d at 496-500.

MGP has also alleged sufficient anticompetitive effects resulting from the attempted enforcement of the Par Patents. A complaint must contain either direct or inferential allegations concerning all the elements necessary for recovery. *Car Carriers*, 745 F.2d at 1106. It is necessary to allege that attempted enforcement of the illegal patents provided economic domination, the power to fix prices, or exclude competitors from the relevant market. *Pollenex*

Corp. v. Sunbeam-Home Comfort, No. 92 C 98, 1992 WL 199080, at *2 (N.D.Ill. Aug.7, 1992), *aff'd*, 39 F.3d 1197 (Fed.Cir.1994). Par counters that MGP has failed to allege Par has market power as result of its patents. MGP must set forth facts sufficient to create an inference that Par has enough market power to establish a monopoly. *Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc.*, No. 01 C 1646, 2001 WL 1001117, at *3 (N.D.Ill. Aug.24, 2001). MGP has done just that, alleging:

(1) [Par] advised MGP and other manufacturers of megestrol acetate oral suspension products that they will license their patents only upon terms that limit the output of competitors to a defined number of units; thereby maintaining artificially high prices. (Am.Compl.¶ 128.)

(2) For example ... Teva settled its litigation on terms that limit its output. (*Id.* ¶ 120.)

(3) Defendant's efforts have restricted output, raised rival costs, and increased market price for generic megestrol acetate products. Defendants have also raised the cost of entry into the market.... (*Id.* ¶ 133.)

Par argues that the complaint is deficient because MGP only alleges that the Par Patents cover certain formulations, uses and methods of manufacture, and that MGP does not allege that the patents are able to drive all or most substitutes from the market. However, whether there may be effective substitutes which do not infringe the patents is a fact to be proven. *Walker Process*, 382 U.S. at 178.

Par also argues that it achieved a seventy-five percent share in the market through entirely legal means and that MGP's allegations fail to connect its market share with attempted enforcement of the Par Patents. *See Mitsubishi Elec. Corp. v. IMS Tech., Inc.*, No. 96 C 499, 1997 WL 630187, at *6 (N.D.Ill. Sept.30, 1997) (allegation of market share alone is insufficient to survive a motion to dismiss). Par points to the six-month exclusivity period it received as the first generic to file an ANDA as well as other advantages such as superior marketing and distribution that allowed it to obtain a strong market position. It is the willful acquisition or maintenance of monopoly power as distinguished from growth or development as consequence of a superior product, business acumen, or historic accident that must be shown. *Elliott v. United Ctr.*, 126 F.3d 1003, 1004-05 (7th Cir.1997). Nevertheless, "[i]mproperly prolonging a monopoly is as much an offense against the Sherman Act as is wrongfully acquiring market power in the first place." *Xechem*, 372 F.3d at 902. Par may initially have acquired market strength via the ANDA exclusivity period or other factors independent of the patents, but this ignores MGP's allegations that Par's subsequent attempt to enforce the patents has had anticompetitive consequences as demonstrated by restricted supply, increased product costs, and competitive barriers.

***10** In sum, MGP has adequately set forth facts sufficient to plead a section two antitrust claim under *Walker Process*. MGP sets forth conduct of knowing and willful omissions of specific material prior art references, as well as prior rejections of claims, which induced the PTO to issue invalid patents. It is alleged that the prior art created a statutory bar to patentability of the subject matter of the claims, and but for the omissions the Par Patents could not have issued. MGP also identifies a relevant market and sufficiently outlines anticompetitive effects within the market resulting from the attempted enforcement of the allegedly invalid patents. Finally, it is asserted that Par's course of action has a dangerous probability of success in monopolizing the market and has caused injury to MGP, other named competitors, and consumers within the market. Therefore, MGP has properly stated a section two antitrust claim under *Walker Process*.

II. The *PRE* Claim

As an alternative to *Walker Process*, MGP also alleges that Par is engaging in sham litigation by attempting to enforce the allegedly invalid or unenforceable Par Patents. In general, the *Noerr-Pennington* doctrine provides immunity to those who petition the government for redress. *PRE*, 508 U.S. at 56; *Pennington*, 381 U.S. at 670; *Noerr*, 365 U.S. at 137-44. However, immunity is withheld where the petition "is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. In *PRE*, the Supreme Court established a two-prong test for determining whether litigation is a sham. 508 U.S. at 60. First, the lawsuit must be objectively baseless such that no reasonable litigant could realistically expect success on the merits. *Id.* Second, "the court should focus on whether the baseless suit conceals 'an attempt to interfere directly with a competitor's business relationships,' through the 'use [of] the governmental *process*-as opposed to the *outcome* of that process-as an anticompetitive weapon." ' *Id.* at 60-61 (citations omitted, emphasis in original). The suit is immunized if an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome. *Id.* at 60. Only if the suit

is found to be objectively baseless may the court proceed to the second prong of the test. *Id.*

A. *PRE'* s Objective Prong

The Court must first determine whether MGP has adequately alleged that Par's litigation is objectively baseless. MGP alleges that Par is prosecuting baseless patent infringement suits involving patents that were procured through knowing and willful fraud, thereby making the patents unenforceable or invalid. (Am.Compl.¶ ¶ 119, 123.) Par is allegedly asserting the unenforceable or invalid patents in objectively baseless lawsuits against MGP, Alpharma USPD Inc., Roxane Laboratories Inc., and Teva Pharmaceuticals, U.S.A. (*Id.* ¶ ¶ 19-22, 124-27.)

***11** Bringing a suit for anticompetitive purposes to enforce a patent that the patentee knows is invalid or not infringed is prohibited under antitrust law. C.R. Bard, 157 F.3d at 1368. MGP alleges, in some detail, that Par knowingly obtained the patents through fraud and that the patents are unenforceable or invalid.[FN3]

> FN3. *See supra* Part I.A of this opinion addressing MGP's allegations of fraudulent procurement of the Par Patents. MGP also asserts that if the conduct does not amount to fraud, the conduct meets the less stringent definition of inequitable conduct. A finding of inequitable conduct renders a patent unenforceable. *See, e.g., Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1569 (Fed.Cir.1992) (inequitable conduct does not invalidate a patent but renders the patent unenforceable).

This Court and other courts have denied motions to dismiss based on similar assertions. *See, e.g., Knoll*, 2001 WL 101117, at *3 (claimant satisfied pleading requirement by alleging they sent letter to patentee prior to lawsuit asserting that patent was invalid and alleging patentee had no reasonable belief that patent would be enforced); *OpenLCR.com, Inc. v. Rates Tech., Inc.*, 112 F.Supp.2d 1223, 1233 (D.Colo.2000) (plaintiff satisfied pleading requirement by alleging that defendant knowingly failed to disclose material prior art to PTO in procuring their patent); *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d. 618, 643-44 (E.D.Mich.2000) (plaintiff satisfied pleading requirement by alleging patent was prosecuted for the purpose of providing a basis to instigate sham patent infringement litigation).

Par correctly points out that its patents carry a presumption of validity, it has a statutory right to enforce its patents, and assertion of a duly granted patent is presumed to be made in good faith. C.R. Bard, 157 F.3d at 1369 (citations omitted). These presumptions merely set forth the parties' evidentiary burdens. Patent invalidity is a statutory defense and the presumption of validity can be rebutted. 35 U.S.C. § 282. On a motion to dismiss, all that is required is that MGP allege facts that, if proved, show Par is engaged in sham litigation. *See Jarrow Formulas, Inc. v. Int'l Nutrition Co.*, 175 F.Supp.2d 296, 310-11 (D.Conn.2001). MGP has sufficiently alleged that the Par patents are invalid. Following Par's argument, a plaintiff asserting a sham litigation claim in the context of a patent infringement suit could never satisfy the objective prong of the *PRE* test.

Par also argues that its prior settlement with Teva for infringement of the '318 patent provides it with a reasonable belief that it can achieve a successful outcome in the present suit. Success in prior litigation clearly provides the litigant with an objective basis for bringing subsequent actions on similar claims. *PRE*, 508 U.S. at 61 n. 5. A favorable prior settlement may afford support for a belief that subsequent litigation will be successful, but it is not dispositive. *See Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 482 (Fed.Cir.1991) (holding that consent judgment as to patent validity must be construed narrowly even between the consenting parties). Parties may settle a litigation for a variety of reasons independent of the merits of the claims. *See, e.g., Fisher v. Kelly*, 105 F.3d 350, 353 (7th Cir.1997) (parties settle for reasons wholly unrelated to the substance and issues involved in the litigation); *Wang Labs., Inc. v. Toshiba Corp.*, 793 F.Supp. 676, 678 (E.D.Va.1992) (hypothesizing that an appeal of patent invalidity may be settled because parties can jointly profit from exploiting a fraudulently procured patent, a result contrary to the patent and antitrust laws). Moreover, the Teva settlement involved only one of the four patents at issue in this case.

B. *PRE* Subjective Prong

***12** Finding that MGP has raised sufficient allegations under the first prong of *PRE*, the Court must determine whether MGP has adequately alleged that Par is attempting to use the litigation process to interfere directly with the business relationships of its

competitors. *PRE*, 508 U.S. at 60-61. MGP alleges that the Par patent infringement suits against it and other competitors are being brought in bad faith, to extort settlements which limit the output of competitors, raise the cost of doing business in the market, raise the cost of entry into the market, and deter customers from purchasing competitive products. (Am.Compl.¶ ¶ 119, 133.)

MGP's Amended Complaint meets the second prong of *PRE* by alleging that Par's purpose in pursuing its infringement claims is to monopolize the market for megestrol acetate oral suspension products by interfering with competitors entering the market. A complaint merely alleging bare legal conclusions cannot survive a motion to dismiss but must at least outline the violation. *Car Carriers*, 745 F.2d at 1106. MGP asserts sufficient facts to outline that Par is attempting to employ the litigation process to assert its allegedly invalid patents to prevent entry of competitors into the market. A complainant cannot be expected to have knowledge of specific facts in regard to a litigant's motivation or intent prior to discovery. *See Poller v. Columbia Broad. Sys.*, 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962) ("[S]ummary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators, and hostile witnesses thicken the plot."); *Car Carriers*, 745 F.2d at 1106 ("*Poller* ... simply stand[s] for the proposition that, if a claim under the antitrust laws has been adequately set forth in the complaint, the highly factual and subjective questions of intent and purpose should be resolved after discovery and trial.").

MGP has adequately set forth the elements necessary to strip Par of its antitrust immunity under *PRE*. MGP has presented detailed allegations that the Par Patents are unenforceable or invalid as result of fraud or inequitable conduct in front of the PTO and that Par is attempting to enforce those patents. MGP has also satisfactorily alleged that Par is undertaking the suits for the purpose of harming competitors. Therefore, MGP has properly stated a claim under *PRE*.

III. Claim for Violation of Section One of the Sherman Act

A contract, combination, or conspiracy in restraint of trade violates section one of the Sherman Act. 15 U.S.C. § 1. A plaintiff must allege: (1) the existence of some contract, combination or conspiracy, (2) an anticompetitive effect in a relevant market resulting from the defendants' actions, and (3) an injury to himself and the market. *Car Carriers*, 745 F.2d at 1107.

First, MGP alleges that Par entered into a contract, combination, or conspiracy when it states: "For example, rather than incur the cost of litigation with Par, Teva settled its litigation on terms that limit its output." (Am.Compl.¶ 120.) Although mere settlement of patent litigation does not violate the antitrust laws, liability arises when settlement is a device for circumventing the antitrust laws. *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F.Supp.2d. 986, 991 (N.D.Ill.2003).

***13** Second, MGP alleges Par and Teva's settlement agreement has an anticompetitive effect. (Am.Compl.¶ 133.) If "firms restrict output directly, price will ... rise in order to limit demand to the reduced supply." *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 594 (7th Cir.1984). "[R]aising price, reducing output, and dividing markets have the same anticompetitive effects." *Id.* at 594-95. Accordingly, "[a]n agreement which has the purpose and effect of reducing output is illegal under § 1 of the Sherman Act." *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 247 (3d Cir.2001).

MGP alleges that the Par-Teva settlement agreement restricted Teva's output, which in turn decreased supply of generic megestrol acetate products and increased their market price. (Am.Compl.¶ 133.) MGP further alleges that Par has sufficient market power (seventy-five percent market share) to raise prices by reducing output (*id.* ¶ 118), and it can be inferred from that allegation that Par has the ability to raise prices above the competitive level without losing all of its business.

Third, MGP has alleged that it has been injured because it has lost sales as a result of Par's violation of section one of the Sherman Act. (Am.Compl.¶ 132.) MGP also alleges that consumers have been injured due to increased prices of generic megestrol acetate products. (*Id.* ¶ 133.) Finally, MGP also states that competition in the generic megestrol acetate industry has been weakened due to the increased cost of entry into the market. (*Id.*)

Viewing MGP's allegations and drawing all reasonable inferences in its favor, the Court holds that the Amended Complaint states a claim for violation of section one of the Sherman Act. Whether

MGP ultimately will be able to prove the elements of a section one claim is not an issue before the Court on a motion to dismiss. Therefore, the Court denies Par's motion to dismiss MGP's claim for violation of section one of the Sherman Act.

CONCLUSION

For the foregoing reasons, the Court denies defendants' motion to dismiss Count VI of the Amended Complaint [doc. no. 45-1].

SO ORDERED

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Briefs and Other Related Documents (Back to top)

- 2006 WL 1045582 (Trial Motion, Memorandum and Affidavit) Par's Memorandum of Law in Opposition to Mgp's Motion for Summary Judgment (Mar. 16, 2006) Original Image of this Document (PDF)
- 2006 WL 740452 (Trial Motion, Memorandum and Affidavit) Morton Grove Pharmaceuticals' Memorandum of Law in Support of its Motion for Summary Judgment (Feb. 21, 2006)
- 2005 WL 3392820 () Rebuttal Expert Report of Dr. Alexander M. Klibanov (Nov. 23, 2005)
- 2005 WL 3616043 (Trial Motion, Memorandum and Affidavit) Morton Grove Pharmaceuticals' Trial Brief (Nov. 23, 2005)
- 2005 WL 3616042 (Trial Motion, Memorandum and Affidavit) MGP's Motion to Compel Documents Par Provided to Its Damages Expert (Nov. 4, 2005)
- 2005 WL 3286686 (Trial Motion, Memorandum and Affidavit) Par's Reply Memorandum of Law in Support of its Motion to Dismiss Count VI of Morton Grove's Amended Complaint (Oct. 12, 2005)
- 2005 WL 2716474 (Trial Motion, Memorandum and Affidavit) Mgp's Response to Par's Motion to Dismiss Count VI of Morton Grove's Amended Complaint (Sep. 23, 2005)
- 2005 WL 2716473 (Trial Motion, Memorandum and Affidavit) Mgp's Reply to Second Amended Counterclaims for Relief (Sep. 14, 2005)
- 2005 WL 2716463 (Trial Pleading) Second Amended Answer and Counterclaims (Aug. 30, 2005)
- 2005 WL 2611042 (Trial Motion, Memorandum and Affidavit) Par's Memorandum of Law in Support of its Motion to Dismiss Count Vi of Morton Grove'S Amended Complaint (Aug. 29, 2005)
- 2005 WL 2612074 (Trial Pleading) Amended Complaint for Declaratory Judgment & other Relief (Aug. 15, 2005)
- 2005 WL 2611033 (Trial Motion, Memorandum and Affidavit) Morton Grove Pharmaceuticals' Memorandum in Support of its Request for an in Camera Review of Certain Documents from Par'S Privilege Log (Jul. 29, 2005)
- 2005 WL 3676892 (Trial Motion, Memorandum and Affidavit) Par's Memorandum of Law in Response to Morton Grove's Motion to Compel The Production of Documents Responsive to Plaintiff's Rule 34 Requests (Jun. 24, 2005)
- 2005 WL 2716472 (Trial Motion, Memorandum and Affidavit) Confidential Pursuant to Protective Order (Jun. 14, 2005)
- 2004 WL 3562983 (Trial Motion, Memorandum and Affidavit) Mgp's Reply to Pri and Par's Counterclaims for Relief (Dec. 27, 2004)
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- 1:04cv07007 (Docket) (Nov. 1, 2004)
- 2004 WL 3642628 (Trial Motion, Memorandum and Affidavit) Par's Memorandum of Law in Opposition to Mgp's Motion to Compel Documents (2004)
- 2004 WL 3642629 (Trial Motion, Memorandum and Affidavit) Par's Trial Memorandum (2004)

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